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Subject: NEWS UPDATES: EPA to Seek Early Advice From All Parties On Studies for Design of IRIS Assessments (BNA)
Date: 09/18/2012 09:43 AM

EPA to Seek Early Advice From All Parties On Studies for Design of IRIS Assessments

By [Pat Rizzuto](#)

The Environmental Protection Agency will seek advice from all parties regarding the studies and analytic approach it will use in preparing toxicological reviews of chemicals and pollutants under its Integrated Risk Information System (IRIS) program, a senior EPA official said Sept. 17.

Before it launches an IRIS assessment, EPA will invite regulated parties, environmental health advocates, communities who may be affected by polluted sites, and other federal agencies to discuss the studies it should use, the health problems the assessment should focus on, and missing information that would be useful, said Kenneth Olden, director of EPA's National Center for Environmental Assessment.

Currently, interested parties comment on IRIS assessments after they are already drafted.

Getting "buy-in on what the rules are" before an assessment begins should eliminate a lot of "back-end debates and discussion," Olden said.

EPA will invite interested parties to comment on the advice it should seek from peer reviewers who evaluate draft IRIS assessments, Olden said. Olden spoke during the first meeting of the National Academies' Committee to Review the IRIS Process.

Reviewing Revised Draft Assessments

EPA also will let interested parties review and comment on IRIS assessments after they have been revised to address concerns raised by the public and peer reviewers but before they are completed, Olden said.

In most cases revised assessments still in the draft stage are distributed to other federal agencies but not to the general public.

That has created a situation where interested parties who are concerned about the conclusions EPA reached in its draft assessment contact other federal agencies to ask those agencies to "carry their water" for them, Olden said. He referred to private parties asking federal agencies to lobby for the private sector viewpoint during interagency discussions.

"I don't think that's healthy if another agency is carrying their water," Olden said. "Why not allow all stakeholders to see the [revised] draft and comment?"

Panel Addressing Previous Criticisms

EPA asked the National Academies' committee to review the process the agency uses to develop IRIS assessments and changes to that process being implemented.

EPA asked the academies' National Research Council to convene the committee after a separate NRC committee, which reviewed EPA's draft assessment of formaldehyde in 2011, said the agency failed to adequately support key conclusions, such as its finding that the chemical causes leukemia and other cancers.

The formaldehyde committee also said IRIS assessments need to consistently examine the strengths and weaknesses of studies they analyze, and it urged EPA to make its assessments, which have sometimes run more than 1,000 pages, more succinct ([69 DEN A-1, 4/11/11](#)).

The formaldehyde critique spurred congressional hearings and prompted appropriators to tell EPA it must incorporate NRC-recommended changes in future IRIS assessments ([243 DEN A-8, 12/19/11](#)).

The IRIS review committee is chaired by Jonathan Samet, a pulmonary physician and epidemiologist from the University of Southern California. He also chaired the committee that reviewed the draft toxicological review of formaldehyde.

EPA's Changes Called 'Revolutionary.'

Three consultants and three officials representing chemical manufacturers spoke during the public comment portion of the meeting, and nearly all supported early public involvement in the process.

"Olden's suggestions would go a long way toward improving the quality of IRIS and eliminating controversy," said Pat Casano, an attorney who works on corporate environmental programs at General Electric Co.

"Olden's suggestions are revolutionary," said Chuck Elkins, president of Chuck Elkins and Associates.

However, he urged the committee to go beyond words as it examines EPA's process of preparing assessments. The committee should examine concerns raised about specific, draft IRIS assessments and whether and how EPA addressed those in its final analyses, Elkins said.

ACC Preparing White Papers

The panel should talk with mid-level staff and people who track IRIS routinely, said Elkins, who once managed EPA's chemicals office while working at the agency for 25 years.

Richard Becker, senior toxicologist at the American Chemistry Council, and Kimberly Wise, senior director for the council's Center for Advancing Risk Assessment Science and Policy, also commended Olden for the changes he announced.

To help the agency and the academies committee, the ACC risk assessment center has commissioned two white papers, Becker said.

The first white paper will examine different ways institutions such as the Organization for Economic Cooperation and Development, the European Center for the Validation of Alternative Methods, and EPA's Office of Pesticide Programs summarize data from laboratory animal, cellular, and other non-human studies.

That paper should be completed in a few weeks, Becker said.

The second white paper will examine various "weight of evidence" strategies, Becker said. That term refers to comparing the contribution different types of scientific information can have toward a final conclusion about a chemical or pollutant.

Weight of Evidence Workshop Planned

Vincent Coglian, acting director of the IRIS program, said during the meeting that EPA often has to compare quite different types of worker, general population, laboratory animal, and cellular tests that have varying degrees of relevance to the ways people may be exposed to a chemical or pollutant and the exposure levels they experience.

The weight of evidence paper should be completed in late fall, Becker said. The committee will hold a workshop in March 2013 on weight of evidence strategies.

The committee will hold its next meeting in December to continue the IRIS evaluation process.

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